

JUL 27 2009

K092122

Section 6: 510 (k) Summary
(As required by 21 CFR 807.92 and 21 CFR 807.93)

510(K) OWNER: DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46582
Establishment Registration Number: 1818910

510(K) CONTACT: Rhonda Myer
Senior Regulatory Affairs Associate
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DATE PREPARED: July 8, 2009

PROPRIETARY NAME: DePuy Global Shoulder StepTech™ Anchor Peg
Glenoid

COMMON NAME: Shoulder Prosthesis

CLASSIFICATION: 21 CFR 888.3660 – Shoulder joint metal/polymer
semi-constrained cemented prosthesis

DEVICE PRODUCT CODE: KWS

**SUBSTANTIALLY EQUIVALENT
DEVICE:** DePuy Global Shoulder Crosslinked Glenoid,
K052472 (October 11, 2005)

DEVICE DESCRIPTION:

The DePuy Global Shoulder StepTech Anchor Peg Glenoid is designed for use as the glenoid component in a total shoulder arthroplasty. The glenoid is manufactured from crosslinked polyethylene conforming to ASTM F648, and is offered in sizes 40, 44, 48, 52 and 56 (bearing diameter and outside profile size) with step heights of +3, +5 and +7 (size of posterior buildup).

INDICATIONS FOR USE:

The StepTech Anchor Peg Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

Glenoid components are intended for cemented use only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject Global Shoulder StepTech Anchor Peg Glenoid has the same indications for and intended use, material, sterilization, packaging, and bearing sizes as the previously-cleared DePuy Global Shoulder Crosslinked Glenoids, K052472. The difference between the subject and predicate device is that the subject glenoid has a step in the backside geometry. Because of these similarities, DePuy proposes that the subject of this submission, the Global Shoulder StepTech Anchor Peg Glenoid, is substantially equivalent to the predicate Global Shoulder Crosslinked Glenoid, cleared in K052472 on October 11, 2005.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DePuy Orthopaedics, Inc.
% Ms. Rhonda A. Myer
Senior Regulatory Associate, Regulatory Affairs
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2009

Re: K092122

Trade/Device Name: Global Shoulder StepTech Anchor Peg Glenoid
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: KWS
Dated: July 9, 2009
Received: July 14, 2009

Dear Ms. Myer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Rhonda A. Myer

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/cdrh/comp/> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Director

Division of Surgical, Orthopedic,
and Restorative Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Section 5: Indications for Use Statement

510 (k) Number (if known): K092122

Device Name: DePuy Global Shoulder StepTech™ Anchor Peg Glenoid

Indications for Use:

The StepTech™ Anchor Peg Glenoid is intended for use in total shoulder replacement surgery for patients suffering from:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

Glenoid components are intended for cemented use only.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Jonathan J. for mym
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092122